



Office of Water (4601M)
Office of Ground Water and Drinking Water
Total Colform Rule (TCR) and Distribution System Issue Papers Overview

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PREPARED FOR:

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Background and Disclaimer

The USEPA is revising the Total Coliform Rule (TCR) and is considering new possible distribution system requirements as part of these revisions. As part of this process, the USEPA is publishing a series of issue papers to present available information on topics relevant to possible TCR revisions. This paper was developed as part of that effort.

The objective of the "white papers" is to review the available data, information and research regarding the potential public health risks associated with the distribution system issues, and where relevant, identify areas in which additional research may be warranted. The white papers will serve as background material for EPA, expert and stakeholder discussions. The papers only present available information and do not represent Agency policy. Some of the papers were prepared by parties outside of EPA; EPA does not endorse those papers, but is providing them for information and review.

Additional Information

The paper is available at the TCR web site at:

http://www.epa.gov/safewater/disinfection/tcr/regulation_revisions.html

Questions or comments regarding this paper may be directed to **TCR@epa.gov**.

Total Coliform Rule (TCR) and Distribution System Issue Papers Overview

The purpose of this paper is to: 1) provide an overview of current Federal and State Distribution System (DS) requirements; 2) provide background information on EPA's decision to revise the TCR and consider additional distribution system (DS) requirements; 3) provide an overview of how the 19 issue papers inform DS risk and the need for potential TCR revisions, and 4) summarize the content of the different TCR and DS issue papers that are available from EPA's website.

1) Overview of current Federal and State DS requirements

Federal Requirements

Total Coliform Rule (TCR)

Routine sampling requirements

Community Water Systems (CWS) and Non-community Water Systems (NCWS) using surface water or ground water must monitor for total coliforms from one (≤ 1000 people) to 480 samples per month depending on population served. For CWS using ground water (GW) serving 1000 or fewer people, the State may reduce the monitoring frequency to once per quarter if the source is deemed protected and is free of sanitary survey defects. NCWS using GW and serving 1000 or fewer must monitor at least each calendar quarter of operation but may monitor as little as once per year if the State determines the system is free of sanitary survey defects. Sampling locations, identified in the sample siting plan, are required to be representative of water throughout the distribution system, including all pressure zones and areas supplied by each water source and distribution reservoir.

Follow-up sampling for initial total coliform positives

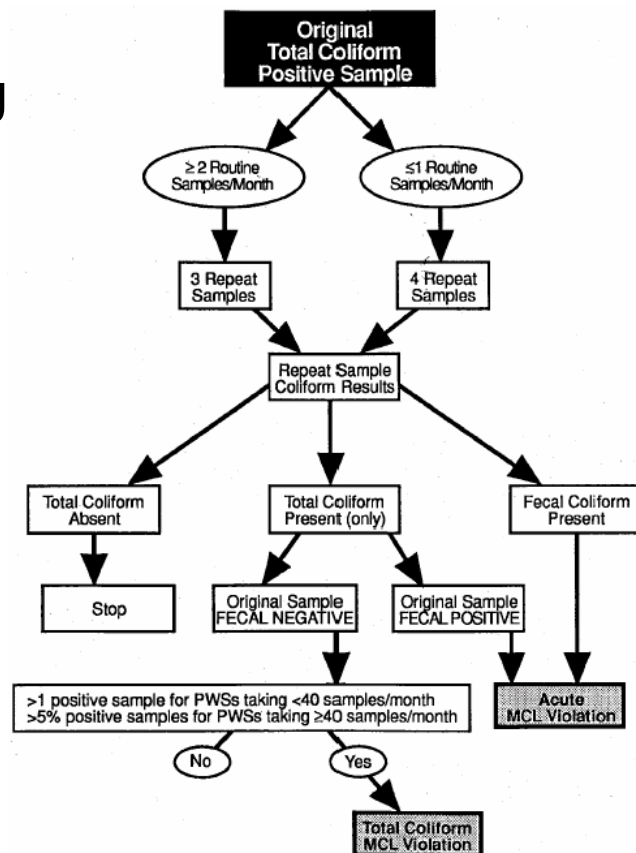
Each sample tested to be total coliform positive must also be tested for either *E.coli* or fecal coliform presence. In addition, systems must collect a set of repeat samples for each total coliform positive. Systems with 1 or fewer routine samples per month must collect 4 repeat samples (one at same tap, one downstream within 5 service connections, one upstream within 5 service connections, and one elsewhere in the DS). Systems with 2 or more routine samples per month must collect 3 repeat samples (one at same tap, one downstream within 5 service connections, one upstream within 5 service connections). Also, during the month following a total coliform positive, systems taking fewer than 5 routine samples per month must take a total of 5 DS samples.

MCL determinations:

- For a system serving more than 33,000 people and collecting more than 40 samples per month, a monthly maximum contaminant level (MCL) violation occurs when more than 5.0 percent of the samples collected during the calendar month are total coliform positive.
- For systems serving 33,000 people or fewer and collecting less than 40 samples per month, a monthly MCL violation occurs when more than one sample is total coliform (TC) positive in a given calendar month.
- For any system, an acute MCL violation occurs when it finds a TC sample positive followed by a repeat sample positive, with at least one of these also being positive for *E. coli* or fecal coliform.

See Figure 1 for an illustration of how MCL determinations are made.

Figure 1 Determining Coliform Maximum Contaminant Level Violations



Surface Water Treatment Rule (SWTR)

The SWTR pertains to all CWS using surface water (SW) or ground water under the direct influence of surface water (GWUDI), sets treatment technique requirements for pathogens originating at the source (*Giardia*, viruses, *Legionella*), and includes specific requirements for the DS. The residual disinfectant concentration in the DS, measured as total chlorine, combined chlorine, or chlorine dioxide cannot be undetectable in more than 5 percent of samples each month, for any two consecutive months that the system serves water to the public. Water in the distribution system with a heterotrophic bacteria plate count (HPC) of less than or equal to 500 colony forming units/milliliter is deemed equivalent to having a detectable disinfectant residual for the purpose of determining compliance with this requirement. Samples for measuring residual disinfectant concentrations or heterotrophic bacteria must be taken at the same locations in the distribution system and at the same time as samples collected for total coliforms.

Lead and Copper Rule (LCR)

The LCR requires corrosion control treatment, lead service line replacement, and public education. The LCR has “action levels” for lead and copper. An action level is exceeded when greater than 10 percent of samples collected from the sample pool contain lead levels above 0.015 mg/L or copper levels above 1.3 mg/L. Water systems exceeding the respective action level are required to install corrosion control treatment and conduct lead service line replacement and mandatory lead education. Worst case condition sampling is required twice a year at 5 to 100 within home distribution system sites depending on system size, with allowance for reduced frequency and sites depending upon levels found.

Stage 1 Disinfection Byproducts Rule (Stage 1 DBPR)

The Stage 1 DBPR applies to all public water systems (PWS) that disinfect, and requires systems to meet MCLs for total trihalomethanes (TTHMs) at 0.080 mg/L, five haloacetic acids (HAA5) at 0.060 mg/L, bromate at 0.010 mg/L, and chlorite at 1.0 mg/L. Compliance with the TTHM and HAA5 MCLs is computed as a running annual average and is based on monitoring in the distribution system. Compliance with the bromate MCL is computed as a running annual average and is based on monitoring prior to the first customer. Compliance with the chlorite MCL is based on individual measurements determined each month, based on screening monitoring at plant and follow-up monitoring in the DS.

The Stage 1 DBPR sets Maximum Residual Disinfectant Levels (MRDLs) for chlorine, chloramines (measured as total chlorine), and chlorine dioxide. For chlorine and chloramines, samples for measuring residual disinfectant must be taken at the same locations in the distribution system and at the same time as samples collected for total coliforms. For chlorine dioxide, samples must be taken daily at the entrance to the distribution system. Compliance with the MRDLs for chlorine and chloramines (4 mg/l) is based on the annual running average of all monthly samples collected, while

compliance with the MRDL for chlorine dioxide (1.0 mg/l) is based on each daily sample.

Interim Enhanced Surface Water Treatment Rule (IESWTR) and Long Term 1 Enhanced Surface water Treatment Rule (LT1)

The IESWTR (for large systems) and LT1 (for small systems) pertain to all CWS using SW or GWUDI and set treatment technique requirements for *Cryptosporidium* originating in the source water. The IESWTR requires States to conduct sanitary surveys (including inspection of DS) for all SW systems and GWUDI within every 3 years for CWS and within every 5 years for NCWS. Systems must report to States how they are addressing significant deficiencies identified by the State. The IESWTR also requires that all finished water storage facilities, for which construction began after February 16, 1999, be covered.

Long Term 2 Enhanced Surface Water Treatment Rule (LT2)

The LT2 Rule pertains to all CWS using SW or GWUDI sets treatment technique requirements for *Cryptosporidium* originating at the source. The LT2 requires PWS with uncovered finished water storage reservoirs to cover the reservoir or treat the reservoir discharge to the distribution system to achieve inactivation and/or removal of at least 2-log *Cryptosporidium*, 3-log *Giardia*, and 4-log virus.

Stage 2 DBPR

The Stage 2 DBPR requires that water systems meet the MCLs for TTHM and HAA5 at each sampling location based on the running annual average of any four consecutive quarterly sample results at that location. To determine the locations within the distribution system where the highest levels of TTHM and HAA5 are expected to occur, the Rule requires water systems to conduct an Initial Distribution System Evaluation (IDSE). IDSEs are studies that evaluate THM and HAA5 levels at various points within the distribution system. The results from these studies along with existing compliance monitoring information will be used to determine future compliance monitoring locations.

Ground Water Rule (GWR)

The GWR sets treatment technique requirements for systems using ground water (i.e., ground water not GWUDI) for pathogens originating in the source water. The GWR requires States to conduct sanitary surveys (including inspection of DS) for all GW systems within every 3 years for CWS and within every 5 years for NCWS. For a CWS, the State may allow the sanitary survey to be conducted every 5 years, if the system provides 4-log inactivation or removal of viruses or has a history of reliable operation and no TCR MCL or reporting violations, as determined by the State. Systems must correct for significant deficiencies identified by the State, including DS deficiencies.

State Requirements

Most states have set requirements for the design, construction, operation, and maintenance of distribution systems. Some states have established mechanisms and delegate resources for implementation while others only encourage certain prevention activities and some states do not address certain contamination issues in distribution systems at all. For example, while 50 states have some requirements for the control of cross-connection and/or backflow prevention, many states do not require an authority to implement a pertained local ordinance or rule and only three states conduct periodic reviews of cross-connection control programs. There appears to be substantial lack of consistency of distribution system requirements set by States.

2) Background on EPA's decision to revise the TCR and consider additional DS requirements

The 1996 amendments to the Safe Drinking Water Act (SDWA) [Section 1412(b) (9)] require EPA to review and revise, as appropriate, each national primary drinking water regulation no less often than every six years.

On April 17, 2002, EPA presented and requested comment on its intent to revise the TCR (67FR19029). The basis for this decision was to consider how to reduce the implementation burden of the existing TCR with possible new requirements for ensuring the integrity of distribution systems. On July 18, 2003 EPA confirmed its decision to revise the TCR including consideration of new requirements for ensuring the integrity of distribution systems (68FR42907). The July Federal Register Notice also stated, in response to public comments, that any consideration for reducing the implementation burden of the TCR should not lead to a reduction in public health protection (SDWA anti-backsliding provision 1412(b)(9)).

In 2000, as part of its recommendations concerning the LT2 and the Stage 2 DBPR, the Stage 2 Microbial/Disinfection Byproducts (M/DBP) Federal Advisory Committee recognized the following points in its Agreement in Principle:

- "Finished water storage and distribution systems may have an impact on water quality and may pose risks to public health."
- "Cross-connections and backflow in distribution systems represent a significant public health risk."
- "Water quality problems can be related to infrastructure problems and that aging of distribution systems may increase risks of infrastructure problems."
- "Distribution systems are highly complex and that there is a significant need for additional information and analysis on the nature and magnitude of risk associated with them."

The M/DBP Federal Advisory Committee concluded from these points that EPA should review and evaluate available data and research on those aspects of distribution systems that may create or pose risks to public health as a part of the Six-Year Review of the Total Coliform Rule. The Advisory Committee also specifically recommended that EPA initiate a process for addressing cross connection control and backflow prevention requirements.

The current TCR requires utilities to take total coliform samples in the distribution system. This monitoring constitutes the majority of distribution system monitoring. While this monitoring may capture and identify several microbial contamination event pathways in the distribution system, it was not designed to capture the range of risks that were identified by the M/DBP Federal Advisory Committee. EPA plans to assess the effectiveness of the current TCR and determine what alternative and/or additional risk reduction strategies are available, and to consider revisions to the TCR with new requirements for ensuring the integrity of the distribution system. To help achieve these goals, it is important to understand 1) DS contamination mechanisms and pathways, 2) how water quality conditions can impact public health, and 3) tools available for, and

issues related to, identifying and assessing potential distribution system public health risks. EPA has developed issue papers that pertain to these categories of interest.

3) Issues Related to Distribution Risk and the TCR revision

Following is a brief summary of the content of the issue papers pertaining to the above three categories. Also, briefly discussed is how the categories relate to each other.

1) Contamination mechanisms and pathways issue papers in this category describe mechanisms and pathways for how contaminants can enter the distribution system. Contaminants can enter the distribution system via intrusion, cross-connections and backflow, permeation and leaching, during main repair or replacement, and unintended access through finished water storage facilities. Five papers elaborate on our current understanding of these respective risk factors.

2) Distribution system water quality conditions that impact public health risk issue papers in this category describe how the water quality within the distribution system can be affected by contamination mechanisms and pathways, and/or underlying water quality and distribution system operations. Areas of focus include microbial growth and biofilm development and release; nitrification; aging infrastructure and corrosion; water age; effects of treatment on nutrient availability (and influence on microbial growth and biofilm); DS infrastructure inventory and integrity; and inorganic contaminant accumulation in the distribution system.

3) Distribution system tools and issues related to identifying and assessing potential public health risk issue papers in this category describe different strategies for monitoring and identifying contamination and deficiencies, and also include tools that assess the effectiveness and reliability of water quality indicators. Overall these tools are a way to look at water quality and public health risk factors that are a result of contamination pathways and/or underlying water quality and distribution system operations. Areas of focus include papers on various aspects of TCR compliance and implementation, DS indicators of water quality, how hazard analysis can inform monitoring and contaminant control strategies, and use of disinfectant residuals as an indicator and contaminant control strategy.

Overall the 19 issue papers categories are interrelated. Contaminants can enter the DS through a variety of pathways and affect water quality, and a variety of tools can be used to assess such impacts. As an example of this interrelationship, Figure 2 illustrates how aging infrastructure impacts main repair and replacement, which in turn impacts microbial water quality. As listed on the figure, the tools that can help to identify and assess public health risk may include indicators of water quality, Hazard Analysis and Critical Control Point (HACCP), effectiveness of distribution system residuals, and distribution system integrity.

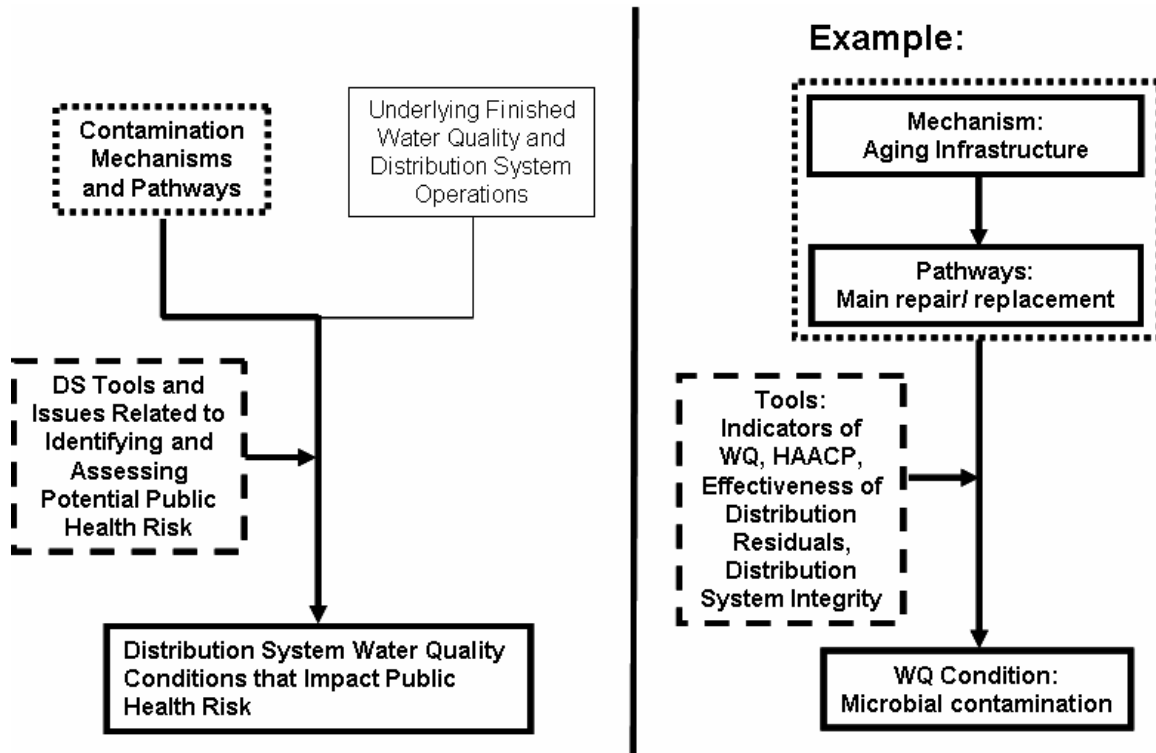


Figure 2. Example of Interrelationships between Distribution System Issues

4) Summaries of Issue Papers

Contamination Mechanism and Pathways

The Potential for Health Risks from Intrusion of Contaminants into the Distribution System from Pressure Transients

This paper describes how pressure transients cause intrusion of contaminants into the distribution system, potential public health risk associated with intrusion, and existing control measures. Pressure transients (which can also lead to backflow) in distribution systems resulting from activities such as valve closures, pipe fractures, or pump stoppage coupled with pipe leaks can provide a pathway for untreated, possibly contaminated groundwater or contaminated water from other sources (e.g. nearby leaking sewer lines) to enter the finished water in the distribution system. Pressure transients are caused by an abrupt change in the velocity of water, which results in an exchange of energy between flow and pressure. This pressure change is exhibited as a wave of increased and decreased pressures. Pathogens or chemicals in close proximity to the pipe can be drawn into the pipes and be a potential contamination source even though they are originated external to the distribution system. Existing control measures for intrusion that are covered by the paper include engineering standards for pipeline and pump design, valve selection and installation, surge tanks, and distribution system network analysis considering pressure transients.

Potential Contamination Due to Cross-Connections and Backflow and the Associated Health Risks

This paper describes cross-connections and backflow and the causes of backflow contamination through cross-connections, as well as strategies for mitigation including discussion of state programs. A cross-connection is a point in a plumbing system where it is possible for a nonpotable substance to come into contact with the potable drinking water supply. Backflow is any unwanted flow of used or nonpotable water, or other substances from any domestic, industrial, or institutional piping system back into the potable water distribution system. The paper also reports on actual contamination events that led to illness. From 1981 to 1998, the CDC documented 57 waterborne disease outbreaks related to cross-connections, resulting in 9,734 illnesses. These include 20 outbreaks (6,333 cases of illness) caused by microbiological contamination, 15 outbreaks (679 cases of illness) caused by chemical contamination, and 22 outbreaks (2,722 cases of illness) where the contaminant was not reported or unknown. Mitigation of backflow contamination covered by this paper includes installing and maintaining backflow prevention devices and assemblies.

Permeation and Leaching

This paper describes permeation and leaching in the distribution system, characterizes contamination due to permeation and leaching, examines the factors that lead to leaching and permeation risk, the indications of these conditions, and mitigation methods. Distribution system infrastructure and appurtenances can react with both water within the pipe and external water, potentially allowing contaminants into the drinking water. Leaching is the dissolution of metals, chemicals, and other materials of the piping and appurtenances into water. Permeation is the movement of chemicals from outside the pipe, through the pipe or appurtenance materials themselves (as opposed to through orifices or leaks, as in intrusion), and into water. Mitigation methods examined in the paper include meeting acceptable pipe material as specified in ANSI/AWWA standards.

New or Repaired Water Mains

This brief paper reviews situations under which microbes and chemicals may contaminate the distribution system as the result of installation of new pipes and/ or repair of existing pipes. The paper provides an overview of information on procedures to prevent contamination during construction and repair from AWWA manuals and the scientific literature. A brief discussion of the risk of waterborne disease associated with contamination of mains and some examples of contamination events that occurred as a result of poor construction or repair practices are presented.

Finished Water Storage Facilities

The paper presents a description of risk due to microbes and chemicals that originate in finished water storage facilities or enter through defects in the finished water storage facilities, and discusses a range of prevention and mitigation measures and indicators of potential problems. Contamination mechanisms and examples of contamination of both external and internal origin are discussed, including contamination from tank materials and coatings, contamination due to faulty design, poor operational practices that allow water to stagnate over long periods of time and inadequate maintenance. Prevention and mitigation measures are the major focus of the paper, including a discussion of tank inspection practices and maintenance and operational activities, and discussion of design of storage facilities. Water quality indicators, water quality monitoring, and modeling are also discussed. Sections on maintenance activities and design of storage include references to standard practices (e.g. AWWA standards for disinfection procedures, ANSI/NSF standards for coatings, and Ten States Standards).

Distribution System Water Quality Conditions that Impact Public Health Risk

Health Risks from Microbial Growth and Biofilms in Drinking Water Distribution Systems

This paper reviews information from the scientific literature relevant to assessing and controlling potential risks associated with growth of bacteria and the presence of biofilms in the distribution system. Biofilms are a complex mixture of microbes, organic and inorganic material accumulated amidst a microbially-produced organic polymer matrix attached to the inner surfaces of distribution systems. The paper includes a discussion of the opportunistic pathogenic bacteria that grow in the distribution system as well as survival of frank pathogens in biofilms and factors that affect associated health risks. The paper discusses factors that affect the presence of microbes in the distribution system, including routes of entry, factors that influence growth, measures to prevent or control microbial growth and entry of microbes into the distribution system. Indicators of potential problems are also discussed.

Nitrification

This paper describes the condition of nitrification, its causes, the potential risk to the public, and how to prevent the condition. Nitrification is a microbial process by which nitrogen compounds (primarily ammonia) are sequentially oxidized to nitrite and nitrate. Ammonia is present in drinking water through either naturally-occurring processes or through ammonia addition during secondary disinfection to form chloramines. While nitrification can degrade water quality, the formation of nitrite, nitrate and disinfection byproducts are the only water quality issues associated with nitrification. Other effects of nitrification, such as reductions in pH and alkalinity, may impact public health less directly, perhaps by resulting in elevated lead or copper

levels. The prevention and mitigation strategies for nitrification are discussed.

Deteriorating Buried Infrastructure

This paper describes why deteriorating water distribution system infrastructure experiences increased leakage; main breaks; taste, odor and color complaints; reduced hydraulic capacity and greater disinfectant demands due to corrosion products and biofilms. The paper examines primary mechanisms of pipe failure: hydraulic transients, internal corrosion, leadite, and material fatigue and includes decision making matrices. How infrastructure deterioration causes contamination to occur is also discussed along with strategies for mitigation such as surge control, operator training, cathodic protection, and joint replacement, depending on the type of pipe failure problem identified in the paper.

Effects of Water Age on Distribution System Water Quality

This paper reviews water quality problems associated with water age that may pose a public health problem. Water age is a major factor that may contribute to water quality deterioration within the distribution system by several mechanisms including: disinfection byproduct formation, nitrification, microbial growth, and corrosion. The prevention and mitigation discussion includes tools for determining water age including tracer studies and models, references of standard design guidelines for hydraulic considerations, and methods to reduce water age by modifying operations, maintenance and source water treatment. The review of indicators of high age discusses different aesthetic indicators and monitoring indicators.

Effect of Treatment on Nutrient Availability

This paper examines the degree to which various types of water treatment may increase nutrient levels and have an affect on water quality in the DS. Some treatment processes can increase nutrients in the distribution systems to a level that may contribute to microbial growth in distribution system biofilms. Ozonation, for example, degrades complex humic substances to small, easily metabolized organic substances that are used for growth and energy by many biofilm organisms.

Distribution System Inventory, Integrity and Water Quality

This paper provides a national picture of the susceptibility of distribution system infrastructure by providing information on different materials used for infrastructure, and an assessment of their conditions (e.g., age, degree of corrosion). Different types of pipe and other infrastructure materials have different susceptibilities to unexpected contamination, and to various infrastructure degradation processes. The paper examines information from multiple surveys, databases, studies, and publications, and identifies data gaps relative to certain types of infrastructure and materials. While the intent of the paper is to address distribution system integrity many of the surveys do not include information on the conditions of the infrastructure.

Inorganic Contaminant Accumulation in Distribution Systems

This paper discusses factors that may lead to contaminant accumulation and subsequent release back into drinking water, and methods for detecting and controlling contaminant release. Inorganic contaminants entering the distribution system either through the treatment process or through other mechanisms can adhere to pipe scales and accumulate within the scales or pipe and storage tank sediments. Biofilms are discussed also. Under some circumstances these inorganic contaminants may be released during times of water chemistry change (e.g. initiation of residual disinfection), or during hydraulic disturbances (e.g., pressure fluctuations). There are documented instances of inorganic contaminants being released from scales or sediments at levels above the Maximum Contaminant Level (MCL), where levels below the MCL existed at entry to the distribution system. By and large, these events likely go undetected due to a lack of sampling in the distribution system.

Distribution System tools and issues related to identifying and assessing potential public health risk

Analysis of Compliance and Characterization of Violations of the Total Coliform Rule

This paper analyzes compliance with the TCR from 1997 to 2005. The paper identifies, on a National, State and EPA Regional basis, the annual MCL and monitoring/reporting violations. Variables include the type of MCL violation (acute versus non-acute), system size category, system type (e.g., non-transient noncommunity water system), and water source. Statistically significant relationships are determined.

Total Coliform Sample Invalidation

This paper identifies the invalidation requirements of the TCR and their rationale, feedback from some states on the approximate number of positive samples being invalidated (and due to what causes), and the approximate percentage of samples being invalidated by laboratories (along with the analytical methods associated with the interference). When promulgating the TCR, EPA recognized that there would be instances where there would be the need to invalidate certain total coliform-positive samples and total coliform-negative samples. At the same time, the Agency was concerned about the potential for systems to regard any positive sample as a sample collection error if repeat samples were negative, and thus, ignore the original sample. Thus, the Agency included constraints in the final TCR for invalidating a positive sample.

Causes of Total Coliform Positive Samples and Contamination Events in Distribution Systems

This paper identifies the factors that can lead to the occurrence of total coliform positives and unexpected contamination events in distribution systems. The factors that are examined include water treatment failures, accidental events (e.g., main breaks), natural events (e.g., significant weather events), operations and maintenance events (e.g., pressure fluctuations), and a host of other events. The paper links these contamination events to documented cases of distribution system contamination, including contaminants such as undesirable chemicals, hazardous substances, pathogens, and total coliform-positive samples, or TCR MCL violations (as identified in EPA's Safe Drinking Water (SDWIS) database, where possible).

Distribution System Indicators of Water Quality

This paper identifies and characterizes potential indicators of distribution system contamination, particularly those related to unexpected contamination of the distribution system. Microbial indicators discussed include total coliforms, fecal coliforms, *E. coli*, enterococci, fecal streptococci, somatic coliphage, f-specific coliphage and heterotrophic bacteria. Various chemical (e.g., sterols, turbidity, AOC) and physical indicators (e.g., water loss, pressure drops) are examined. Data indicating a potential relationship between public health risk and the indicators are discussed.

Evaluating HACCP Strategies for Distribution System Monitoring, Hazard Assessment and Control

This paper reviews information and data regarding the use of HACCP in the U.S. and other countries for identifying locations in the distribution system that are most susceptible to contamination and thus critical for safeguarding public health. The paper discusses how monitoring and contamination prevention and control strategies can be developed through HACCP. It has been used in drinking water distribution systems in some European countries, Australia, New Zealand, and in some locations in the U.S.

A Review of Distribution System Monitoring Strategies under the Total Coliform Rule

This paper examines potential monitoring strategies with a focus on those strategies that are independent of the HACCP approach. The paper reviews current TCR approaches (e.g., State-approved sampling plans) and a range of existing sampling criteria (e.g., sample volumes used, disinfectant residual sampling at the point of TCR sampling). The paper explores alternative monitoring approaches to the existing strategies, such as the number of samples being based on a statistical determination of number of samples needed. This information can be used to identify monitoring

strategies that may provide the same level of public health protection as the current TCR at potentially less cost and resource burden.

The Effectiveness of Disinfectant Residuals in the Distribution System

This paper reviews the existing literature, research and information to inform the effectiveness of disinfectant residuals in the distribution system. The paper focuses on the effectiveness of residuals to control biofilm, indicate distribution system upsets, and inactivate contaminants that may enter the distribution system. The paper reviews disinfection CT (concentration and contact time) for a range of pathogens under conditions that may mimic those in distribution systems.